

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/908,867	08/08/1997	ANDREW A. YOUNG	227/166	9959
44638 7	590 01/20/2005		EXAM	INER
	PORTER LLP (18528)		CANELLA,	KAREN A
555 TWELFTE	•		ART UNIT	DARED MILITER
WASHINGTO	N, DC 20004		ARTONII	PAPER NUMBER
			1642	
			DATE MAIL ED. 01/20/200	•

Please find below and/or attached an Office communication concerning this application or proceeding.

Requested copy attached.

FORM PTO-1	449		1	ATTY. DOCKET!	١		IAL NO 908,86	•	
	ATENTS AND OTHER ITEMS FOR A FORMATION DISCLOSURE STATEM			APPUCANT: Andrew Young et al.	1	Jul.	- 00,00	•	
	(Use several sheets if necessary)	AU5 0 3 K	~1	FILING DATE: August 8, 1997		GR0	OUP:		
		P. Car	<u>ji</u>						
		I.S. PATENT D	OCUM	ENTS	 -			,	
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	-	NAME	a	ASS	SUB CLASS		LING DATE
fr.H	5,264,372	11/23/93		Beaumont et al.	\bot			 	
批计	5,424,286	06/13/95		Eng	╬			 	
	FOR	EIGN PATENT	DOC	JMENTS		_			
EXAMINER					CLA		SUB	TRANS	LATION
INITIAL	DOCUMENT NUMBER	DATE		COUNTRY	100	*	CLASS	YES	NO
ALH	WO 95/07098	16.03.95	PCT		╀		National Assessment		
			-		╁	\dashv			-
					\vdash	\dashv	-		-
	· · · · · · · · · · · · · · · · · · ·				╁╌	十			\vdash
					<u> </u>				
ALH	Daniel et al. "Use of Glu					," B	r. Med	_L, 3:	720,
ALH	D'Alessio et al. "Elimin of glucose tolerance afte 97:133-38, 1996								ment
Arit	Eissele et al. "Rat Gastri Truncated Glucagon-Lik							lin-4 a	ınd
Alt	Eng et al. "Purification a from <i>Heloderma horridu</i>						etagogi	ie Isol	ated
MIH	Eng et al. "Isolation and Heloderma suspectum V					Anal	logue, i	from	
AUI	Fehmann et al. "Stable E Binding Characteristics Exendin(9-39)," Peptide	Utilizing GL	P-I(7-3	36)-Amide, Oxyntomo					and
ALH	Ferguson et al. "Cell-Su Structures", Annu. Rev.				lphos	phat	idylino	sitol	
MH.	Glauser et al. "Intraveno J. Am. Coll. Emergency				nagea	Fo	od Obs	tructio	מי",
prit	Gedulin et al. "Comparis Inhibit Pentagastrin-Stin (Abstract 1181) (1997) 8	nulated Gastr							
AH	Goke et al. "Exendin-4 I Antagonist at the Glucag Cells", <u>I. Biol. Chem.</u> , 2	gon-like Pepti	ide 1-(7-36)-amide Receptor					
EXAMINER:	Anne L'Hollerau			DATE CONSIDERED:) 7	-11	3/e-	5	•
									

EXAMINER: Ane L'Holleran DATE CONSIDERED: 12/13/3	وس

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

FORM, I	PTO-14	49		ATTY. DOCKET 1	SERIAL NO. 08/908,867			
LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT C. /				APPLICANT: Andrew Young et al.	SERIAL NO. 08/908,867 Tiny Allo GROUP: 1642	10 C		
		(Use	e several sheets if necessary	FILING DATE: August 8, 1997	GROUP: 1642	20		
		_	OTHER DOCUMENTS (Including Author, Ti	tle, Date, Pertinent Pages, Etc.)		ું જ		
A.H			Kolligs et al. "Reduction of the Incretin e Receptor antagonist Exendin(9-39) Amid					
AH		Malhotra et al. "Exendin-4, a new peptide from Heloderma suspectum venom, potentiates cholecystokinin-induced amylase release from rat pancreatic acini", Regulatory Peptides, 41:149-56, 1992						
ALH			Montrose-Rafizadeh et al. "Structure-function Analysis of Exendin-4 / GLP-1 Analogs", Diabetes, 45(Suppl. 2):152A, 1996					
ALH			O'Halloran et al. "Glucagon-like peptide- acid secretion in man," J.Endocrinol 126 (al inhibitor of gastric			
ALH	•		Orskov et al. "Biological Effects and Met and glucagonlike Peptide-1 7-37 in Health 42:658-61, 1993			!		
AUH			Raufman et al. "Truncated Glucagon-like Dispersed Acini from Guinea Pig Pancrea			:		
MH			Raufman et al. "Exendin-3, a Novel Pepti with Vasoactive Intestinal Peptide Recept Acini from Guinea Pig Pancreas," J. Biol.	ors and a Newly Described	Receptor on dispersed			
MH			Scarpignato et al. "Action of Caerulein on Pharmacodyn. Ther. 246:286-94 1980	gastric emptying of the Con	nscious Rat", Arch Int.			
ALIT			Schepp, et al. "Exendin-4 and exendin-(9-39)NH ₂ : agonist and antagonist, respectively, at the rat parietal cell receptor for glucagon-like peptide-1-(7-36)NH ₂ ," Eur. J. Pharm. 269:183-91, 1994					

Schjoldager et al. "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-1, Fragments of

Singh et al. "Use of 1251-[Y39] exendin-4 to characterize exendin receptors on dispersed

pancreatic acini and gastric chief cells from guinea pig," Regul. Pepl. 53:47-59, 1994

Stower et al. "A trial of glucagon in the treatment of painful biliary tract disease," Br. L.

Thorens et al. "Cloning and Functional Expression of the Human Islet GLP-1 Receptor,"

Wang et al. "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," J. Clin. Invest.,

Wang, Y.J. and Hanson, M.A. "Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers," Journal of Parenteral Science and Technology, Technical Report No. 10,

Wettergren et al. "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and

Thorens, "Expression cloning of the pancreatic β cell receptor for the gluco-incretin hormone

Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," Dig Dis Sci 34 (5): 703-8,

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Pancreatic Functions in Man," Dig Dis Sci 38 (4): 665-73, 1993

glucagon-like peptide 1," Proc. Natl. Acad. Sci. USA 89:8641-45, 1992

1989

Surg., 69:591-2, 1982

95:417-21, 1995

Supp. 42:2S, 1988

Diabetes 42 (11): 1678-82, 1993

MH

AH

ALH

MI

MUH

FUH

FORM PTO	-1449	•	ATTY. DOCKET I	SERIAL NO.	1
LIST OF	PATENT NFORM	TS AND OTHER ITEMS FOR APPLICANT'S ATION DISCLOSURE STATEMENT O	227/166 APPLICANT:	08/908,867	-
	(Us	se several sheets if necessary)	Andrew Young et al. FILING DATE: August 8, 1997	GROUP: 1642	
		Lator use dell'			
		OTHER DOCUMENTS (Including Author, Ti	lle, Date, Pertinent Pages, Et	c.)	
AH		Willms et al. "Gastric Emptying, Glucose Test Mel: Effects of Exogenous Glucagor (Noninsulin-Dependent) Diabetic Patients	-Like Peptide-1 (GLP-1)-	(7-36) Amide in Type 2	
		ВООКЅ			7
-		Cohen, S.A., Meys, M., and Tarrin, T.L. (Advanced Techniques for Amino Acid Ar MA).	1989), The Pico Tag Meth alysis, pp. 11-52, Millipo	nod: A Manual of re Gorporation, Milford,	
		Introduction to Cleavage Techniques, App	lied Biosystems, Inc., 19	90, pp. 6-12.	
		Sambrook, et al., Molecular Cloning: A.L. 1989.			1
•			•	÷	
•					ignormal Angleighte
					300 A
		•			HARLES CONTROL
					and the second

EXAMINER: (Mu L'Holleran DATE CONSIDERED: 12/13/60

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

	, -			U.S. PATENT DOCU	MENTS	·	න	,
Examiner Initials*	Cite No.1	U.S. Pater	nt Document Kind Code ² (# Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	0/29(ř
	-					, garas, gaas	8	
	 	 			·			

				FOREIGN F	PATENT DOCUMENTS			
			Foreign Patent Doc		Name of Patentee or	Date of Publication	Pages, Cohures, Lines, Where Relevant	
Examiner Initials	Cite No.	Office'	Number ⁴	Kind Code (y		of Cited Document MM-DD-YYYY	Passagns or Relevant Figures Appear	
KAC	5	wo	98/30231		Amylin Pharmaceuticals, Inc.	07-16-1998		
KAL	1	wo	99/07404		Amylin Pharmaceuticals, Inc.	02-18-1999		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	L,
		BAYER et al., "Advances in Poison Management," Clin. Chem., 42(8)(B):1361-66 (1996)	
	{	D'ALESSIO et al., "Glucagon-like Peptide 1 Enhances Glucose Tolerance Both by Stimulation of Insulin Release and by Increasing Insulin-independent Glucose Disposal," J. Clin. Invest., 93:2263-66 (1994)	
	1	HOLST, "Glucagonlike Peptide-1: A Newly Discovered Gastrointestinal Hormone," <u>Gastroenterology</u> , 107:1848-55 (1994)	
4	ì	LAWLER et al., "Comparison of Effects of Amylin, Glucagon-like Peptide-1 (GLP-1) and Exendin-4 to Inhibit Pentagastrin-Stimulated Gastric Acid Secretion in Rats," <u>Gastroenterology</u> , 112(4):A194, (1997)	

Examiner Signature of Camella	Date Considered	12/9/03

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will very depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

KAC.	MIHOLIC et al., "Glucagon-like Peptide-1 (GLP-1), Entleerung des Magenersatzes und das Dumpingsyndrom nach Gastrektomie," Chirurgishes Forum, 1991, pp. 429-32 (English abstract and International Search Report in which the article is referenced are attached) NAUCK et al., "Effects of Subcutaneous Glucagon-like Peptide 1 (GLP-1 [7-36 Amide]) in Patients with Type 2-Diabetes," Diabetologia, Abstract A148, 38 Supp. 1:A39 (1995)	ART
	1:A39 (1995) ORSKOV et al., "Is the Effect of Glucagon-like Peptide-1 on Gastric Emptying Centrally Mediated?", <u>Diabetologia</u> , Abstract A147, 38 Supp. 1:A39, (1995)	7
KAC	RITZEL et al., "GLP-1 [7-36 Amide] Augments Bisphasic Insulin Secretion After Intravenous Glucose in Healthy Volunteers," <u>Diabetologia</u> , Abstract A145, 38 Supp 1:A39, (1995)	Soo mode
	· · · · · · · · · · · · · · · · · · ·	
	·	
	·	

1

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Substitute for form 1449A/PTO

(use as many sheets as necessary)

of

2

	Complete If Known	RECE	VED
Application Number	08/908,867	HEOD	
Filing Date	April 10, 2002	0 (2003
First Named Inventor		JAN 0	1 -
Group Art Unit	1642	TECH CENTE	Macinan I
Examiner Name	Holleran	TECH CENTE	K 1000 con
Attorney Docket Numb	er 030639.0040.CPA1	ISOLIARIA	

	U.S. PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	U.S. Patent Document Number Kind Code ² (# known)		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Ratevant Passages or Relevant Floures Appear				

FOREIGN PATENT DOCUMENTS										
Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or	Date of Publication	Pagra, Cohames, Lines, Where Relevant	Т		
		Office ³	Number ⁴	Kind Code [*] (If known)	Applicant of Cited Document	of Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T.		
		WO	98/05351		Amylin	02-12-1998				
KAL	-			- 1	Pharmaceuticals,					
/010					Inc.					
				ļ						

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
KAL	-	NAVARRO, M. et al., "Colocalization of Glucagon-Like Peptide-1 (GLP-1) Receptors, Glucose Transporter GLUT-2, and Glucokinase mRNAs in Rat Hypothalamic Cells: Evidence for a Role of GLP-1 Receptor Agonists as an Inhibitory Signal for Food and Water Intake," <u>Journal of Neurochemistry</u> , 67:1982- 1991 (1996)				
		·				

Examiner Signature	aren !	Gamella	Date Considered	12/9/13

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.